

ARCOS Reporter Training

Drug Enforcement Administration
Office of Diversion Control

www.DEAdiversion.usdoj.gov

April 2016

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- ∨ Introduction
- ∨ Reporting Overview
 - ∨ Filing Reports
- ∨ Understanding Errors
- ∨ ARCOS NDC Dictionary
- ∨ Transaction Records
 - ∨ Resources
 - ∨ Questions

Introduction

Drug Enforcement Administration



Office of Diversion Control



Registration and Program Support



ARCOS Unit

Office of Diversion Control

- *Mission* -

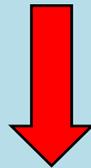
... prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

Controlled Substances Act



Title 21 U.S. Code, Section 827

Manufacturers and Distributors are required to report controlled substances transactions to the Attorney General. The Attorney General delegates this authority to the Drug Enforcement Administration (DEA).



Automation of Reports and Consolidated Orders System (ARCOS)

ARCOS Unit

... **CAN** assist with:

- ü Understanding how to report
- ü Technical issues with reporting systems
 - ü Problem solving

... **CANNOT** assist with:

- L Filing reports on behalf of reporter
- L Granting exemptions or extensions
- L Issues outside of ARCOS (including Registration)

Updating Contact Information

NOTE: It is the responsibility of the ARCOS reporter to keep DEA (i.e. the ARCOS Unit) updated with current contact information and changes to reporting status

ALSO: Please keep the ARCOS Unit updated on associated labeler codes

Updating Contact Information

Paper Request Form

ARCOS PARTICIPANT INFORMATION UPDATE



REGISTRATION #: _____ COMPANY NAME: _____

INFORMATION UPDATED:

_____ CONTACT INFORMATION (*PART A*) _____ REPORTING STATUS (*PART B*)

PART A:

CONTACT NAME: _____ CONTACT PHONE: _____

CONTACT EMAIL ADDRESS: _____

PART B:

REPORTING FREQUENCY: ___ QUARTERLY ___ MONTHLY

REPORTING STATUS: _____ SINGLE REPORTER _____ CENTRAL REPORTING (see below)

Additional Notes

Updating Contact Information

ARCOS Online

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF DIVERSION CONTROL

[Logout](#) [User Manual](#)

ARCOS Web: Main Menu

Reports

Additional Notes

Updating Contact Information

Failure to keep contact information up to date can lead to correspondence issues, including delinquency notices, error reports, and other important notifications and announcements

Reporting Overview

Title 21 U.S. Code and Title 21 Code of Federal Regulations



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

OFFICE OF DIVERSION CONTROL

 Search

HOME

REGISTRATION

REPORTING

RESOURCES

ABOUT US

Report Illicit Pharmaceutical Activities
RX Abuse Online Reporting



Registration Support

Call: 1-800-882-9539 (8:30 am-5:50 pm ET)
Email: DEA.Registration.Help@usdoj.gov
Locate Field Registration Specialists

New Applications

Renewal Applications

Registration Changes (Address, Drug Code, Name, Schedule)



Reporting Overview

21 U.S.C. § 827(a)(3)

“... every registrant ... manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him ...”

21 U.S.C. § 827(b)

“... shall be in accordance with, and contain such relevant information as may be required by ... regulations of the Attorney General”

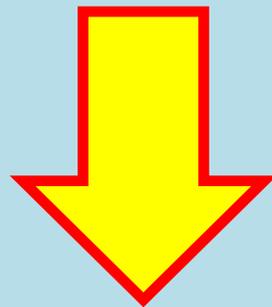
“... shall be maintained separately from all other records of the registrant”

21 U.S.C. § 827(b)

“... in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant”

“... shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.”

21 U.S.C. § 843(a)(4)(A)



**Corresponding violations to
21 U.S.C. § 827**

- **Administrative actions**
 - **Fines and penalties**
 - **Loss of registration**

Who Reports to ARCOS?

Manufacturers

Repackagers*

Relabelers*

Distributors

Reverse Distributors

*Per 21 U.S.C. § 802(15), these activities are considered “manufacturing”

What is Reported to ARCOS?

C-I, C-II, C-III NARCOTICS, AND GAMMA-HYDROXYBUTYRIC ACID PRODUCTS (C-III)

- Ø DOSAGE FORM AND BULK MANUFACTURING
- Ø PACKAGING AND REPACKAGING
- Ø LABELING AND RELABELING
- Ø ACQUISITION AND DISTRIBUTION
- Ø REVERSE DISTRIBUTION
- Ø END-OF-YEAR INVENTORY

What is Reported to ARCOS?

21 C.F.R. § 1304.33(d)(1)

Ø MANUFACTURING ACTIVITIES INVOLVING
SELECTED PSYCHOTROPIC DRUGS IN C-III AND C-IV

Ø END-OF-YEAR INVENTORY OF SELECTED PSYCHOTROPIC
DRUGS IN C-III AND C-IV IF USED IN MANUFACTURING

What is Reported to ARCOS?

ALSO ...

Ø NO ACTIVITY FOR THE REPORTING PERIOD

Ø NO INVENTORY AT THE END OF THE YEAR

Ø THEFT AND LOSS

Ø IN-PROCESS INVENTORY

Ø RETURNS

Ø WASTE

Ø DESTRUCTION

Ø SAMPLES

Ø Not sure? Call the ARCOS Unit!!! 202-307-8600

Repackaging and Relabeling

**MUST CONTACT THE FOOD AND DRUG
ADMINISTRATION (FDA)**

General Email: EDRLS@fda.hhs.gov

- ∅ Do not use the original manufacturer's NDC
 - ∅ Must obtain a unique labeler code

Reporting Frequency

Quarterly OR Monthly

Ø *ONLY PICK ONE*

Ø Must file report even if no activity for period (Trans Code "7")

Reporting Frequency

End-of-Year Inventory

- Ø Quarterly Reporters: Part of 4th quarter report
- Ø Monthly Reporters: Part of December report
 - Ø Different from YERS (Quota)
- Ø Reportable materials on hand as of December 31st
- Ø Must report even if no inventory (Trans Code "8")

Reporting Frequency

Manufacturing Activity

Ø Cumulative, at the end of the year

OR

Ø Quarterly, if permission is granted
(21 C.F.R. § 1304.33(b))

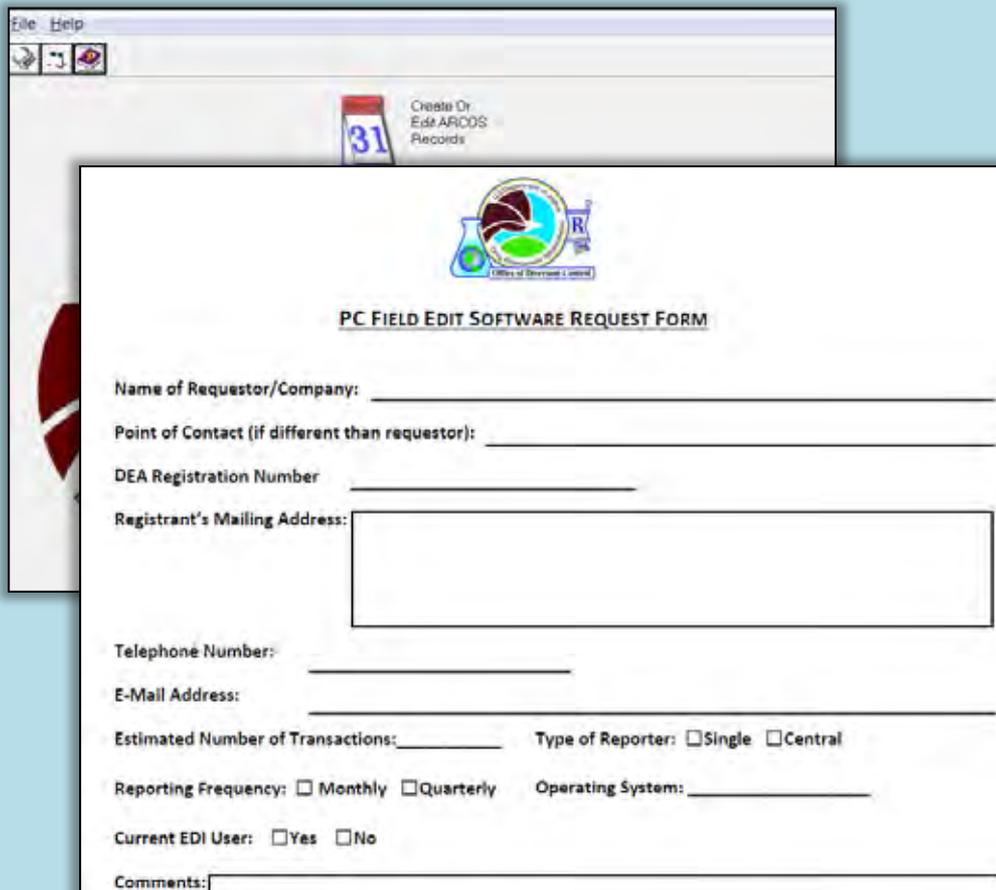
Filing Reports

Methods of Filing Reports

ELECTRONIC

MANUAL

PC Field Edit Software



File Help

Create Or Edit ARCOS Records

31


Office of Government Control

PC FIELD EDIT SOFTWARE REQUEST FORM

Name of Requestor/Company: _____

Point of Contact (if different than requestor): _____

DEA Registration Number _____

Registrant's Mailing Address: _____

Telephone Number: _____

E-Mail Address: _____

Estimated Number of Transactions: _____ Type of Reporter: Single Central

Reporting Frequency: Monthly Quarterly Operating System: _____

Current EDI User: Yes No

Comments: _____

Ø Phase-out beginning Nov. 2015 with release of ARCOS Online

Ø Limited functionality with newer versions of Windows

Ø No plans for upgrades

Ø EDI upload will require own method of creating text file report

Reporting Electronically

EDI Upload – Text File

ARCOS Online

(launched 11/2015)

Methods of Filing Reports

EDI Upload

ELECTRONIC

ELECTRONIC

- ∅ Must be in text format
- ∅ Phase out of PC Field Edit
- ∅ Other means of generating text file
- ∅ Most appropriate for large volume

Methods of Filing Reports



ARCOS Online

- ∅ Releasing in “phases”
- ∅ First phase – eliminate PC Field Edit software
- ∅ Future phases – increase integration with EDI uploads and error corrections

Methods of Filing Reports



MANUAL

DEA Form 333

- ∅ Must be requested
- ∅ Data entry = takes longer
- ∅ No “scanning machine”
- ∅ Human error factor
- ∅ Good back-up option

Single vs. Central Reporting

Single

Default reporting
method

One registration

Central

Field office permission
required
(21 C.F.R. § 1304.04)

Records at central
location

Multiple registrations

Reporting On Time

Reports are due the 15th day of the month following the end of the reporting period (per 21 C.F.R. § 1304.33(b))

Extensions cannot be granted by the ARCOS Unit

Reporting On Time

NOTE: EDI print-out is **not** confirmation that the report has been processed

Reporting On Time

DATE: 10/16/15

CONFIRMATION OF PROCESSED REPORT:

- Ø Daily Transactions Processing print-out
- Ø Screenshot of "Submitted" status (ARCOS Online)
- Ø Downloaded .pdf or text file (ARCOS Online)

↓ Download 80 Char String File

Reporting Exceptions

DEA cannot grant exceptions to requirements imposed by the Controlled Substances Act (CSA)

21 U.S.C. § 827(d): Reporting of controlled substance activity as required by the Attorney General

Reporting Exceptions

HOWEVER ...

DEA may grant an exception from the ARCOS reporting provisions of 21 C.F.R. § 1304.33 to the extent that they go beyond what is required by statute (per 21 C.F.R. § 1307.03)

Reporting Exceptions

Exception requests must be directed to the Deputy Assistant Administrator in charge of the Office of Diversion Control

Until or unless an exception to reporting is granted, reporting will be required

Record Retention

- **21 C.F.R. § 1304.04(a) = “at least 2 years”**

Title 21 Code of Federal Regulations

PART 1304 — RECORDS AND REPORTS OF REGISTRANTS

GENERAL INFORMATION

§1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

Record Retention

➤ However, referencing 21 C.F.R. § 1307.02 ...

Title 21 Code of Federal Regulations

PART 1307 — MISCELLANEOUS

GENERAL INFORMATION

§1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

If State law requires a longer record retention period, it is expected that records for that period will be available

Complete & Accurate

Understanding Errors

Error Transactions

- **Unable to process, versus erroneous or inaccurate transactions**
- **“Complete and accurate” reporting required by law (per 21 U.S.C. § 827)**
- **If not addressed timely, can lead to penalties**

Requesting Deletion

- ∅ Can the reporter correct the error?
- ∅ Checking for patterns of abuse – submitting requests every two years?
- ∅ State record retention requirements considered (per 21 C.F.R. § 1307.02)
- ∅ Field office concurrence

Requesting Deletion

Requests are handled on a case by case basis!!!

**IT IS BEST TO TRY TO CORRECT ALL ERRORS ...
... CALL THE ARCOS UNIT FOR ASSISTANCE**

Correcting Errors

***PAPER FORM AND EDI UPLOAD =
CORRECTION NUMBER***

***ARCOS ONLINE =
NO CORRECTION NUMBER***

Correcting Errors

PAPER FORM AND EDI UPLOAD

| Reporting Registrant | Trans. Code | Action Ind. | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|-----------|----------------------------|-------------------|-------------|-------------------|----------------|-----------|------------------|
| AA9999999 | PD | 000543751* | 000000024 | BB9999999 | 000453890 | 001311997 | 91070022 | 09000000000088 | | |

Correcting Errors

PAPER FORM AND EDI UPLOAD

NOTE: FAILING TO INCLUDE THE CORRECTION NUMBER WILL RESULT IN THE CREATION OF A NEW TRANSACTION, AND THE ERROR TRANSACTION WILL REMAIN UNCORRECTED!!!

Correcting Errors

ARCOS Online



Office of Diversion Control

OFFICE OF DIVERSION CONTROL

Welcome, | [Logout](#)

ARCOS Web: Main Menu

Enter Reports

Enter Corrections

Enter New NDC Number

Correcting Errors

ARCOS Online

Enter Corrections

Help

| Error Transactions | | | | | |
|--------------------|-------------|----------|----------|---|-----------|
| Code | NDC | Qty | Date | Error Text | Options |
| Select | | | | | |
| P | 000544650** | 00000018 | 20120412 | Order form number is required for schedule 1 and 2 drugs. | ^ Correct |
| P | 004065755** | 00000544 | 20120412 | Order form number is required for schedule 1 and 2 drugs. | ^ Correct |
| P | 552530072** | 00000001 | 20120412 | Order form number is required for schedule 1 and 2 drugs. | ^ Correct |
| P | 428580802** | 00000050 | 20120412 | Order form number is required for schedule 1 and 2 drugs. | ^ Correct |
| P | 590110420** | 00000100 | 20120412 | Order form number is required for | ^ Correct |

Correcting Errors

ARCOS Online

Enter corrections

Errors for this transaction:
Order form number is required for schedule 1 and 2 drugs.

Transaction

Trans Code Key (Enter '=' to set a field to the value from the most recently entered transaction, which is shown below) Help

| Trans Code | NDC Number | Quantity | Unit Code | Strength | Assoc. Reg. # | Order Form # | Trans Date |
|------------|------------------------|----------|------------|----------|---------------|--------------|------------|
| P | 00054 -4650 -*** | 18 | -Optional- | | | | 4/12/12 |

Submit Correction Cancel

Understanding Errors

Correcting Errors

ARCOS Online

NOTE: The ARCOS Online system will detect errors as they are entered; HOWEVER, there will be an ability to query old, uncorrected errors and errors generated by the addition of new NDCs

Most Common Errors

Top 20 Errors (as of 2/2016)

| Rank | Code | Total | % of Total | Official Error Description |
|------|------|---------|------------|---|
| 1 | E76 | 732,598 | 41.61% | NDC number is not in the drug file |
| 2 | E16 | 223,775 | 12.71% | Transaction Date outside reporting period and submitted without an Action Indicator |
| 3 | E38 | 161,104 | 9.15% | Strength is not null/0 or 1000, then Quantity must be 1 |
| 4 | E53 | 105,878 | 6.01% | Order Form Number is required for schedule 1 and 2 drugs |
| 5 | E61 | 81,488 | 4.63% | The Transaction ID has an incorrect length (must be 10 and zero fill). |
| 6 | E48 | 68,421 | 3.89% | Associate Registrant Number is not in the CSA master file |
| 7 | E52 | 64,311 | 3.65% | Order Form Number has not been correctly entered |
| 8 | E45 | 55,386 | 3.15% | Transaction Code requires a valid Associate Registrant Number |
| 9 | E31 | 52,934 | 3.01% | Unit must be blank, D, or K with this NDC number |
| 10 | E13 | 46,841 | 2.66% | Transaction Date must be the last day of the reporting month or quarter |

Most Common Errors

Top 20 Errors (as of 2/2016)

| Rank | Code | Total | % of Total | ANOTHER EXPLANATION |
|------|------|---------|------------|--|
| 1 | E76 | 732,598 | 41.61% | The ARCOS Unit has not received this product information |
| 2 | E16 | 223,775 | 12.71% | The Transaction Date was from a prior period with no Action Indicator included |
| 3 | E38 | 161,104 | 9.15% | NDC requires Strength of blank, zero, or 100% for Quantity greater than 1 |
| 4 | E53 | 105,878 | 6.01% | Transactions for C-I and C-II drugs require an Order Form Number |
| 5 | E61 | 81,488 | 4.63% | Transaction length is incorrect, resulting in incorrect length of Transaction Identifier |
| 6 | E48 | 68,421 | 3.89% | Invalid or missing Associate Registrant Number (see E45) |
| 7 | E52 | 64,311 | 3.65% | Invalid Order Form Number |
| 8 | E45 | 55,386 | 3.15% | Invalid or missing Associate Registrant Number (see E48) |
| 9 | E31 | 52,934 | 3.01% | NDC requires Unit to be blank, D (dozens), or K (thousands) |
| 10 | E13 | 46,841 | 2.66% | Transaction Date must be last day of the month or quarter, depending on frequency |

Most Common Errors

Top 20 Errors (as of 2/2016)

| Rank | Code | Total | % of Total | Official Error Description |
|------|------|--------|------------|---|
| 11 | E35 | 20,764 | 1.18% | Strength must be blank for bulk finished or 0001 to 1050 for bulk raw |
| 12 | E33 | 19,063 | 1.08% | Unit must be 5 or 6 with this NDC number |
| 13 | E46 | 16,452 | 0.93% | Associate Registrant Number is invalid for Transaction Codes Y, G, or Z |
| 14 | E32 | 13,969 | 0.79% | Unit must be 1, 2, 3, or 4 with this NDC number |
| 15 | E29 | 13,389 | 0.76% | Quantity must be greater than zero |
| 16 | E40 | 10,028 | 0.57% | Transaction code is invalid. (See the ARCOS handbook for valid codes.) |
| 17 | E37 | 9,993 | 0.57% | Strength must be blank |
| 18 | E12 | 9,529 | 0.54% | Transaction Date contains an invalid month and/or an invalid day |
| 19 | E42 | 8,557 | 0.49% | Transaction Code requires the Associate Registrant Number to be blank |
| 20 | E47 | 8,454 | 0.48% | Associate Registrant Number and Reporting Registrant Number can't match |

Most Common Errors

Top 20 Errors (as of 2/2016)

| Rank | Code | Total | % of Total | ANOTHER EXPLANATION |
|------|------|--------|------------|--|
| 11 | E35 | 20,764 | 1.18% | Strength must be blank for bulk finished product; 0001 - 1050 (0.1% - 105% for bulk raw) |
| 12 | E33 | 19,063 | 1.08% | NDC requires Unit to be 5 (milliliters) or 6 (liters) |
| 13 | E46 | 16,452 | 0.93% | Codes Y (destruction), G (Gov't supplied), or Z (seizure) require authorized registrant |
| 14 | E32 | 13,969 | 0.79% | NDC requires Unit to be 1 (micrograms), 2 (milligrams), 3 (grams), or 4 (kilograms) |
| 15 | E29 | 13,389 | 0.76% | Quantity cannot be zero; Contact ARCOS Unit for assistance |
| 16 | E40 | 10,028 | 0.57% | Invalid Transaction Code |
| 17 | E37 | 9,993 | 0.57% | Strength field error; Contact ARCOS Unit for assistance |
| 18 | E12 | 9,529 | 0.54% | Invalid Transaction Date |
| 19 | E42 | 8,557 | 0.49% | Transaction Code requires blank Associate Registrant Number field |
| 20 | E47 | 8,454 | 0.48% | Associate Registrant Number cannot be the same as Reporting Registrant Number |

Other Errors Worth Noting

| Code | Official Error Description |
|------|--|
| E15 | Transaction Date is later than the run date |
| E28 | Quantity must be numeric |
| E14 | Transaction Code requires a year-end date in the Transaction Date |
| E06 | Action Indicator must be blank, A, I, or D |
| E49 | Associate Registrant Number is not valid for the Transaction Code |
| E36 | Strength must be blank or numeric |
| E34 | Unit must be blank, D, K, 1, 2, 3, 4, 5, or 6 |
| E75 | NDC number is invalid. It contains one or more spaces |
| E22 | Correction Number is not in the error file; The transaction is deleted |
| E23 | Transaction has already been corrected; Please do not submit it again |
| E77 | NDC number is not ARCOS reportable; Don't submit corrected transaction |
| E60 | The transaction record is a duplicate |

Other Errors Worth Noting

| Code | ANOTHER EXPLANATION |
|------|--|
| E15 | Transaction Date was in the future when the report was filed |
| E28 | Invalid Quantity |
| E14 | Transaction Code requires December 31 st as the Transaction Date |
| E06 | Invalid Action Indicator |
| E49 | Conflict between Associate Registrant Number and Transaction Code; contact ARCOS Unit for assistance |
| E36 | Invalid Strength |
| E34 | Invalid Unit |
| E75 | Invalid (i.e. improperly formatted) NDC |
| E22 | Correction Number not found; This transaction was ignored |
| E23 | Error was already corrected; This additional attempt to correct it was ignored |
| E77 | NDC represents non-reportable material; Transaction was not processed |
| E60 | This was a duplicate transaction and was not processed |

ARCOS NDC Dictionary

ARCOS NDC Dictionary

Transactions cannot be processed unless the National Drug Code (NDC) is in the ARCOS dictionary

MANUFACTURERS: Please send product labels to the ARCOS Unit!!!

NDC in ARCOS Format

**LABELER
CODE**

**PRODUCT
CODE**

**PACKAGE
CODE**

12345 - 0123 - 01

5

4

2

Converting to ARCOS Format

Using ZERO FILL in Each Section

ORIGINAL **12345 - 123 - 1**

ARCOS **12345 - 0123 - 01**

ORIGINAL **1234 - 5678 - 12**

ARCOS **01234 - 5678 - 12**

Non-Reportable vs. Non-Scheduled

NON-REPORTABLE

- Scheduled substances, not reportable to ARCOS
- Can be added to ARCOS dictionary, though not required
- Adding to dictionary may help avoid future errors

NON-SCHEDULED

- Cannot be added to ARCOS dictionary
- Attempting to report will always result in error
- “Controlled Substance Schedules” on DEA Diversion website

Non-Reportable vs. Non-Scheduled

NON-REPORTABLE

Examples

- **Anabolic steroids**
- **Alprazolam**
- **Some Codeine preparations**
- **Ketamine**

NON-SCHEDULED

Examples

- **Acetaminophen**
- **Promethazine**
- **Pseudoephedrine
(List 1 Chemical)**
- **Dextromethorphan**

Use of Generic NDCs

“G” number

“Pseudo” NDCs

- **Import and Export documentation**
- **Reverse Distributors – acquisition for destruction and actual destruction**
- **Manufacturing; Research and Development**
 - **Non-commercial only!**
 - **Contact ARCOS Unit for listing**

Submitting Labels or Documentation

- **Email to ARCOS_Unit@usdoj.gov**
- **Fax to 202-307-8612**
- **Upload via ARCOS Online reporting system**

Transaction Records

Control Record – Report Header

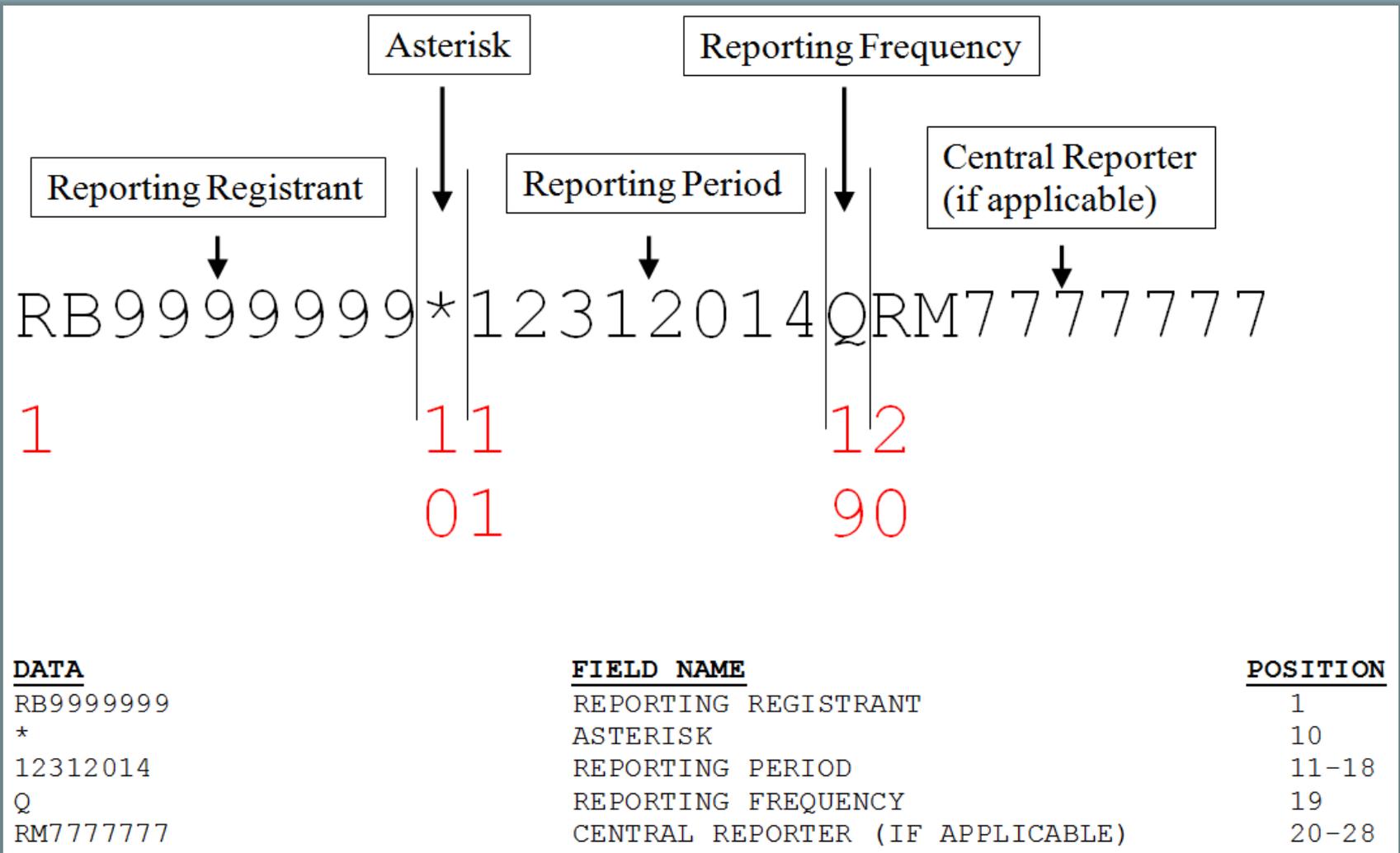
TEXT FILE VIA EDI UPLOAD

RP99999999*09302015Q

| | | |
|-------------|----------------------|------------|
| RP99999999S | 12345012301000000002 | RE88888888 |
| RP99999999P | 02468024602000000005 | BT77777777 |
| RP99999999P | 02468024602000000001 | AP1234567 |
| RP99999999P | 12345012301000000003 | RF7654321 |
| RP99999999S | 12345012301000000002 | RE88888888 |

Transaction Records

Control Record – Report Header



Control Record – Report Header

REPORTING REGISTRANT

Required ... Must reflect registration on which the report is being filed, and must match reporting registrant in each transaction line.

ASTERISK

Required (placeholder) ... Failure to include will result in an improperly formatted Control Record.

REPORTING PERIOD

Required ... For monthly reporters, must be last day of month reported. For quarterly reporters, must be last day of quarter reported.

REPORTING FREQUENCY

Required ... Can only be "M" for monthly reporters or "Q" for quarterly reporters. Anything else in this field will prevent the report from processing.

CENTRAL REPORTER

Not always needed ... Only use when subsidiary of Central Reporter. Otherwise, leave blank.

Transaction Records

Control Record – Report Header

ARCOS ONLINE

The screenshot displays the 'Office of Diversion Control' web application. At the top, there is a 'Welcome,' message and a 'Logout' link. Below this, there is a button labeled ': Add/Edit Report'. A red box highlights the 'Reporting Period:' label and a dropdown menu currently showing '-Select Date-'. Below the dropdown is an 'Add Transaction' button. At the bottom, there is a table titled 'Transactions' with columns for Trans ID, Code, NDC, Qty, Units, Str., Assoc., Ord. Form#, and Date. The table currently shows 'No records found'.

| Trans ID | Code | NDC | Qty | Units | Str. | Assoc. | Ord. Form# | Date |
|------------------|------|-----|-----|-------|------|--------|------------|------|
| No records found | | | | | | | | |

Transaction Records

Control Record – Report Header

PAPER FORM – DEA FORM 333

Drug Enforcement Administration ▶ See mailing instructions on reverse. ◀

ARCOS TRANSACTION REPORTING

CONTROL RECORD
(Complete **ONLY** on First Page of Report or each Subsidiary for Central Report)

| Reporting Registrant Number | Asterisk | Last Day of Reporting Period | Reporting Frequency | Central Reporter's Registration Number (if applicable) |
|-----------------------------|----------|------------------------------|---------------------|--|
| 1 2 3 4 5 6 7 8 9 | 10 * | M M D D Y Y Y Y | M or Q | 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 |

| | | | | | | | | | | | | | | | | | | | | | | | |
|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | A | B | C | D | E | F | G | H | I | J | K | L | M | N |
| No. 0 | No. 1 | No. 2 | No. 3 | No. 4 | No. 5 | No. 6 | No. 7 | No. 8 | No. 9 | Letter A | Letter B | Letter C | Letter D | Letter E | Letter F | Letter G | Letter H | Letter I | Letter J | Letter K | Letter L | Letter M | Letter N |

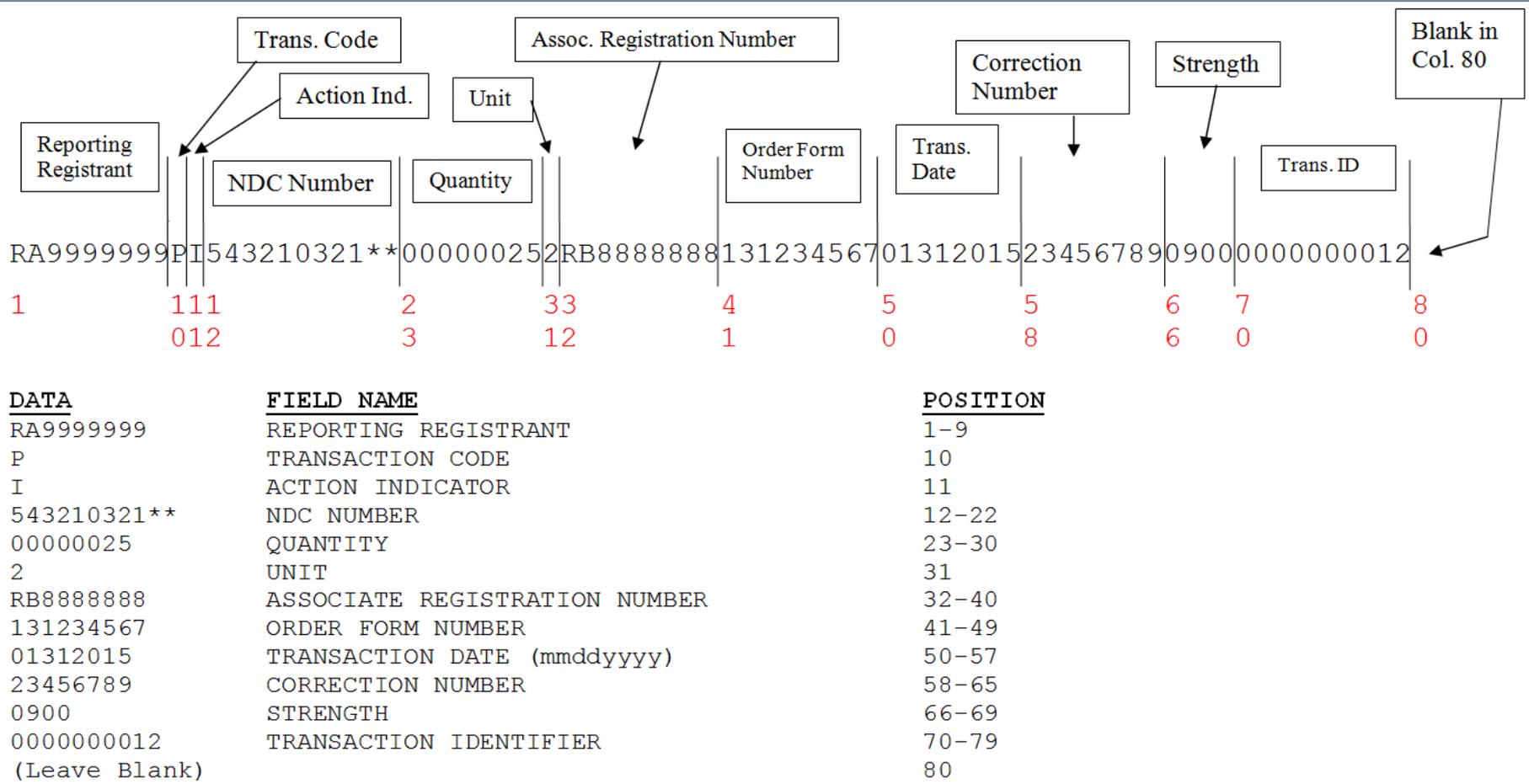
| | | | | | | | | |
|----|----|--------------------|---------|-----|------------------|----|------------------------|-----------------------|
| TC | AI | NATIONAL DRUG CODE | | | QUANTITY | UN | ASSOCIATE REGISTRATION | DEA ORDER FORM NUMBER |
| RO | CN | LABELER | PRODUCT | PKG | Nbr. of Packages | N | NUMBER | |

Control Record – Report Header

❖ Common mistakes:

- Using Reporting Frequency other than “M” or “Q”
- Submitting prior to end of reporting period
- Using invalid end-of-period date
- Not using 8-digit date format
- Unnecessary use of Central Reporter field

80-Character String



Reporting Registrant

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|----------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

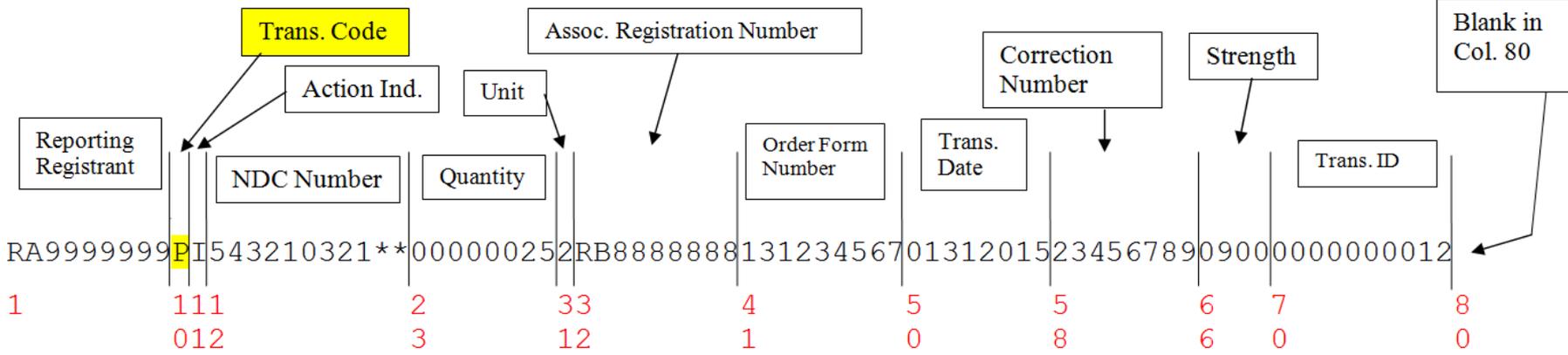
RA9999999 P I 543210321** 00000025 2 RB8888888 131234567 01312015 23456789 0900 000000012
 1 111 2 33 4 5 5 6 7 8
 012 3 12 1 0 8 6 0 0

Reporting Registrant

- **This is only needed in formatting a text file report for upload through EDI**
- **Must match the registration indicated in the Control Record (header) of the report**

Transaction Code

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|-----------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |



Transaction Code

➤ Required for all transactions, using all methods of reporting

➤ List and description of valid codes, along with examples, can be found in Section 5 of the ARCOS Registrant Handbook

❖ **Common mistake: Mixing up the Transaction Code with the Action Indicator**

Transaction Code: Acquisitions

CODE “P” = Purchase or other receipt
Physical change of possession
Establishing initial inventory
Not necessarily monetary
Avoid confusing with “Returns”

Transaction Code: Acquisitions

**CODE “R” = Return at request of
Manufacturer or Distributor**

Includes credit and recall

Not necessarily monetary

New Order Form required

Transaction Code: Acquisitions

CODE “V” = Unsolicited return (i.e. not requested)

When shipper is unknown ...

- **No prior issuance of order form**
- **No identifying markings indicating name of sender**
- **“UNKNOWN” in Associate Registrant field of transaction**

Transaction Code: Acquisitions

CODE “V” = Unsolicited return (i.e. not requested)

When shipper is unknown ...

- **“After the fact” order form must be acquired for C-I and C-II drugs (with field office approval)**

Transaction Code: Acquisitions

CODE “V” = Unsolicited return (i.e. not requested)

When shipper is known ...

- **No prior issuance of order form**
- **“After the fact” order form must be acquired for C-I and C-II drugs (with field office approval)**

Transaction Code: Acquisitions

CODE "G" = Receipt of Government-supplied controlled substances

Includes return of seized material

Registration number of DEA or FDA office, "OFFICER," or

"CIVILDEF" in Associate

Registrant Number field

Transaction Code: Dispositions

CODE "S" = Sale or transfer out

Not necessarily monetary

Does not include quality control sampling (manufacturing)

Physical change of possession

Transaction Code: Dispositions

**CODE “Y” = Accidental or deliberate
destruction**

**To be reported by registrant
conducting destruction**

**Local DEA office registration as
Associate Registrant**

**DEA Form 41 required for
significant losses (contact field
office for advice)**

Transaction Code: Dispositions

CODE “T” = Reporting theft from premises
Must complete DEA Form 106
Different from “in-transit”
theft or loss (see Code “X”)

Transaction Code: Dispositions

**CODE “Z” = Receipt by or transfer to
Government**

**Includes samples taken or
seizures**

**Associate Registrant must be
that of Government office or,
if not available, “OFFICER”**

Transaction Code: Inventory

CODE “1” = Inventory of product that becomes reportable due to schedule change

At the direction of DEA

Not commonly used – contact ARCOS Unit if uncertain

Transaction Code: Inventory

CODE “3” = Physical inventory of reportable products on-hand as of December 31st

Transaction Date must be December 31st

One transaction line for each product (i.e. NDC) on-hand

4th quarter or December report

Transaction Code: Inventory

**CODE “4” = In-process, year-end inventory,
reported by Manufacturers only**

**In production process on
December 31st**

**Transaction Date must be
December 31st**

4th quarter or December report

Transaction Code: Inventory

CODE “5” = Special inventory, not included in the definition of any other inventory transaction code

Do not use unless instructed to do so by DEA

Not commonly used – contact ARCOS Unit if uncertain

Transaction Code: Inventory

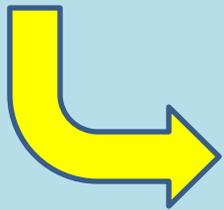
CODE “8” = No reportable product on-hand as of December 31st

Required if not using Codes “3” or “4” in order to receive credit for end-of-year inventory

Only needs to be used once

Transaction Code: Manufacturing

The United States is a signatory to the (a) Single Convention on Narcotic Drugs, 1961, and (b) Convention on Psychotropic Substances, 1971, and as such is required to provide yearly manufacturing statistics to the United Nations (UN) International Narcotics Control Board. As a result, ARCOS was originally designed to capture manufacturing statistics for the United Nations.



Manufacturing activities must be reported to ARCOS on at least an annual basis to comply with United Nations requirements

Transaction Code: Manufacturing

CODE “M” = Used by narcotic and psychotropic manufacturers that synthesize a controlled substance to produce ...

- **Bulk powder material**
- **Bulk quantities of formulated but non-packaged product**
- **Large quantities of product in solution w/ known concentration**

Transaction Code: Manufacturing

CODE “W” = Recovery of waste, returned to inventory

- **Raw powder or dosage form product accumulated, held for later processing**
- **Residue recovered, collected in storage for later destruction**

Transaction Code: Manufacturing

CODE “L” = Recovery of original bulk narcotic and psychotropic substances from preparations for future use

Transaction Code: Manufacturing

CODE “Q” = Reporting the removal of a manufactured product sample for stability testing or other sampling needs

CODE “J” = Reporting the return of a product sample to inventory following stability testing or other sampling needs

Transaction Code: Manufacturing

CODE “K” = For psychotropic substances ...

**Reporting activity involving
utilization of selected
psychotropics to produce ...**

- **Exempt chemical preparations
(21 C.F.R. § 1308.24)**
- **Excluded non-narcotic substances
(21 C.F.R. § 1308.22)**

Transaction Code: Manufacturing

CODE “K” = For psychotropic substances ...

**Reporting activity involving
utilization of selected
psychotropics to produce ...**

- **Exempt prescription products
(21 C.F.R. § 1308.32)**

Transaction Code: Manufacturing

CODE “K” = For narcotic substances ...

Reporting amount of narcotics used to produce ...

- **C-III, C-IV, or C-V preparations of the same narcotic**
- **Any exempt chemical preparations listed in 21 C.F.R. § 1308.24**

Transaction Code: Manufacturing

CODE “N” = Reporting of non-recoverable narcotic or psychotropic substances lost due to accidental spillage or inherent chemical reaction

- **This waste cannot be returned to the original manufacturing process**

Transaction Code: Manufacturing

CODE “U” = For psychotropic substances ...

- **Used to capture the conversion of a psychotropic material to a non-psychotropic substance**

For narcotic substances ...

- **Captures the conversion of one narcotic to another**

Transaction Code: Manufacturing

For additional assistance with Manufacturing reporting, please email the ARCOS Unit a detailed explanation of the activity ...

... the ARCOS Unit may then need to forward that information to the Drug and Chemical Evaluation Section for further guidance

Transaction Code: Manufacturing

Exception to Reporting Manufacturing

- When a quantity of a drug is used to produce an end product containing the same drug in the same schedule, no ARCOS reporting is necessary
- If, however, the process creates waste, samples are taken, or another manufacturing activity occurs, this would still need to be reported

Transaction Code: Other Codes

CODE “7” = No reportable activity for the reporting period

Required to receive credit and avoid delinquency

Only needs to be used once

Transaction Code: Other Codes

CODE "X" = Reporting loss or theft while in-transit

Accompanies sales transaction

Must file DEA Form 106

Intended recipient is Associate Registrant

Explanatory code only – does not affect inventory

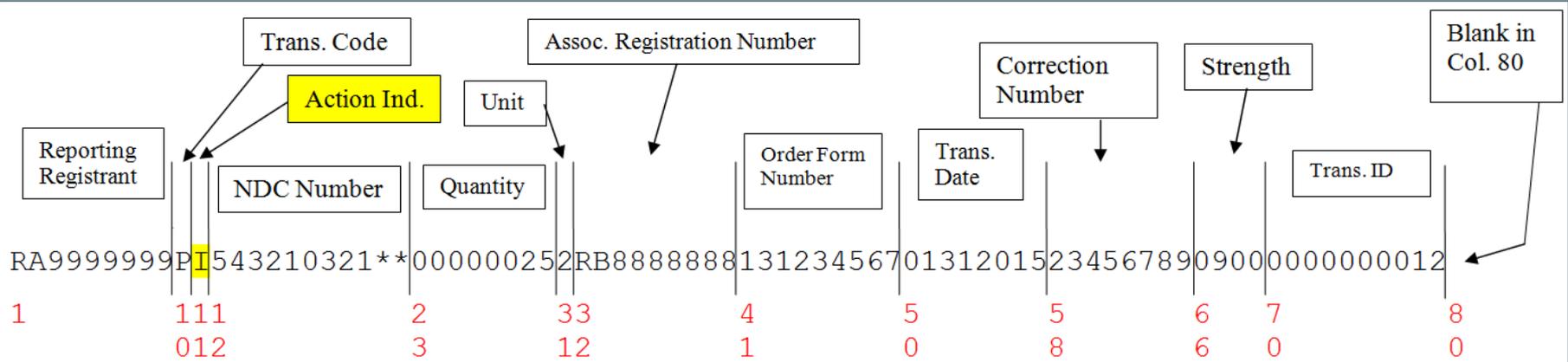
Transaction Code: Other Codes

CODE “F” = Do not use!!!

**Contact ARCOS Unit by
phone or email if DEA
Form 333 is needed**

Action Indicator

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|-----------|
| RA99999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB88888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |



1 111 2 33 4 5 5 6 7 8
 012 3 12 1 0 8 6 0 0

Action Indicator

- **Only needed when reporting via EDI upload or paper form**
- **ARCOS Online: Simplified handling of deletions, adjustments, and insertions**

Action Indicator

➤ Only used in 3 instances ...

- “I” = Insert a transaction that occurred prior to the current reporting period
- “D” = Delete a previously submitted, non-error transaction
- “D & A” = Adjust a previously submitted, non-error transaction (requires two transactions)

Action Indicator

Example: Adjustment Using "D"/"A" Pairing

| Reporting Registrant | Trans. Code | NDC Number | Quantity | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|----------|------|----------------------------|-------------------|-------------|-------------------|----------|-----------|------------------|
| RP99999999 | PD | 12345012301 | 00000002 | | RB88888888 | | 12012015 | | | 000000012 | |
| RP99999999 | PA | 12345012301 | 00000005 | | RB88888888 | | 12012015 | | | 000000012 | |

- **DELETION:** The first line is the transaction as it was originally submitted, with a "D" added in the Action Indicator field

Action Indicator

Example: Adjustment Using "D"/"A" Pairing

| Reporting Registrant | Trans. Code | NDC Number | Quantity | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|----------|------|----------------------------|-------------------|-------------|-------------------|----------|-----------|------------------|
| RP99999999 | PD | 12345012301 | 00000002 | | RB88888888 | | 12012015 | | | 000000012 | |
| RP99999999 | PA | 12345012301 | 00000005 | | RB88888888 | | 12012015 | | | 000000012 | |

- **ADJUSTMENT:** The second line is the transaction as it should be corrected, with an "A" added in the Action Indicator field

Action Indicator

Example: Adjustment Using "D"/"A" Pairing

| Reporting Registrant | Trans. Code | Action Ind. | NDC Number | Unit | Quantity | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|-------------|------|----------|----------------------------|-------------------|-------------|-------------------|----------|------------|------------------|
| RP99999999 | P | D | 12345012301 | | 00000002 | RB88888888 | | 12012015 | | | 0000000012 | |
| RP99999999 | P | A | 12345012301 | | 00000005 | RB88888888 | | 12012015 | | | 0000000012 | |

- *In this example, the Quantity is changing from 2 packages to 5 packages*

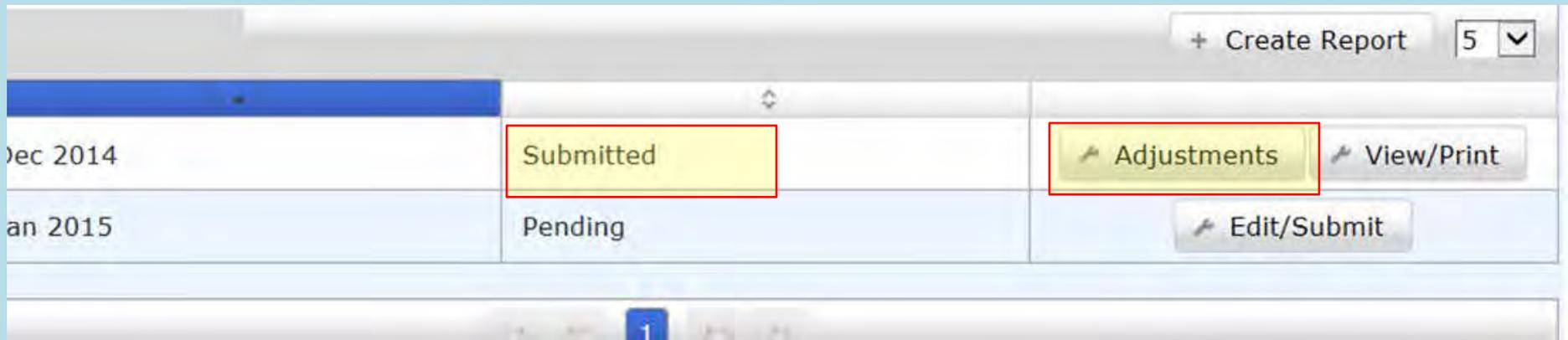
Action Indicator

❖ Common mistakes:

- Trying to use Action Indicator “D” to delete an error transaction
- Trying to use Action Indicator “A” to adjust a transaction without using Action Indicator “D”

Action Indicator

INSERT, ADJUST, or DELETE – ARCOS ONLINE



The screenshot shows a web interface for ARCOS Online. At the top right, there is a '+ Create Report' button and a dropdown menu showing '5'. Below this is a table with two rows. The first row is for 'Dec 2014' and has a 'Submitted' status, an 'Adjustments' button, and a 'View/Print' button. The second row is for 'Jan 2015' and has a 'Pending' status and an 'Edit/Submit' button. The 'Submitted' status and the 'Adjustments' button are highlighted with red boxes.

| Month | Status | Actions |
|----------|-----------|-------------------------|
| Dec 2014 | Submitted | Adjustments, View/Print |
| Jan 2015 | Pending | Edit/Submit |

- *In ARCOS Online, additions, deletions, and changes are entered directly into the submitted report*

Action Indicator

INSERT, ADJUST, or DELETE – ARCOS ONLINE

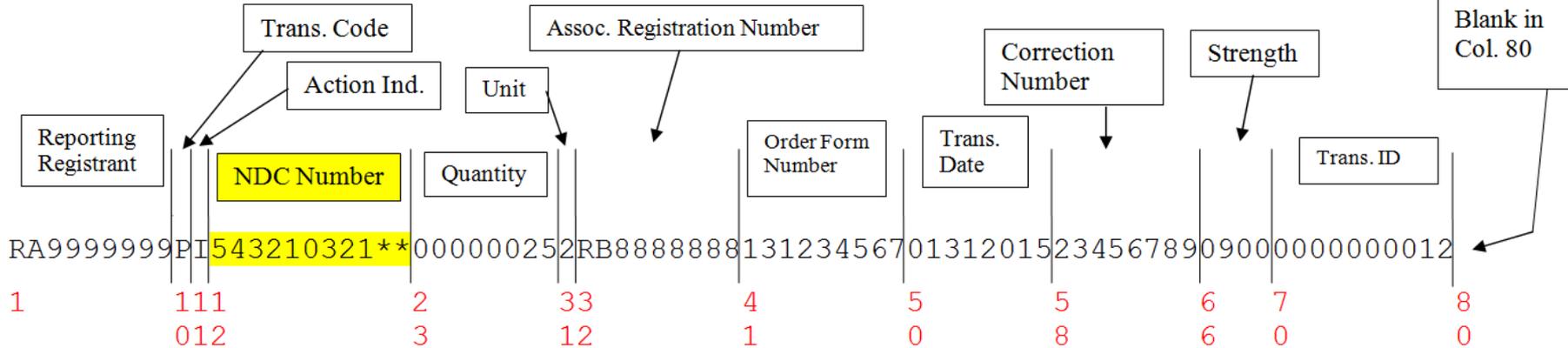
| Transactions | | | | | | | | | |
|--------------|------|-------------|-----|-------|------|----------|------------|------------|---|
| Trans ID | Code | NDC | Qty | Units | Str. | Assoc. | Ord. Form# | Date | Options |
| 1 | G | G11000150** | 12 | 2 | 12 | MILITARY | | 2014-12-18 | <input type="button" value="Adjust"/> <input type="button" value="Delete"/> |

(1 of 1) 1 10

- *In ARCOS Online, additions, deletions, and changes are entered directly into the submitted report*

National Drug Code (NDC)

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|----------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

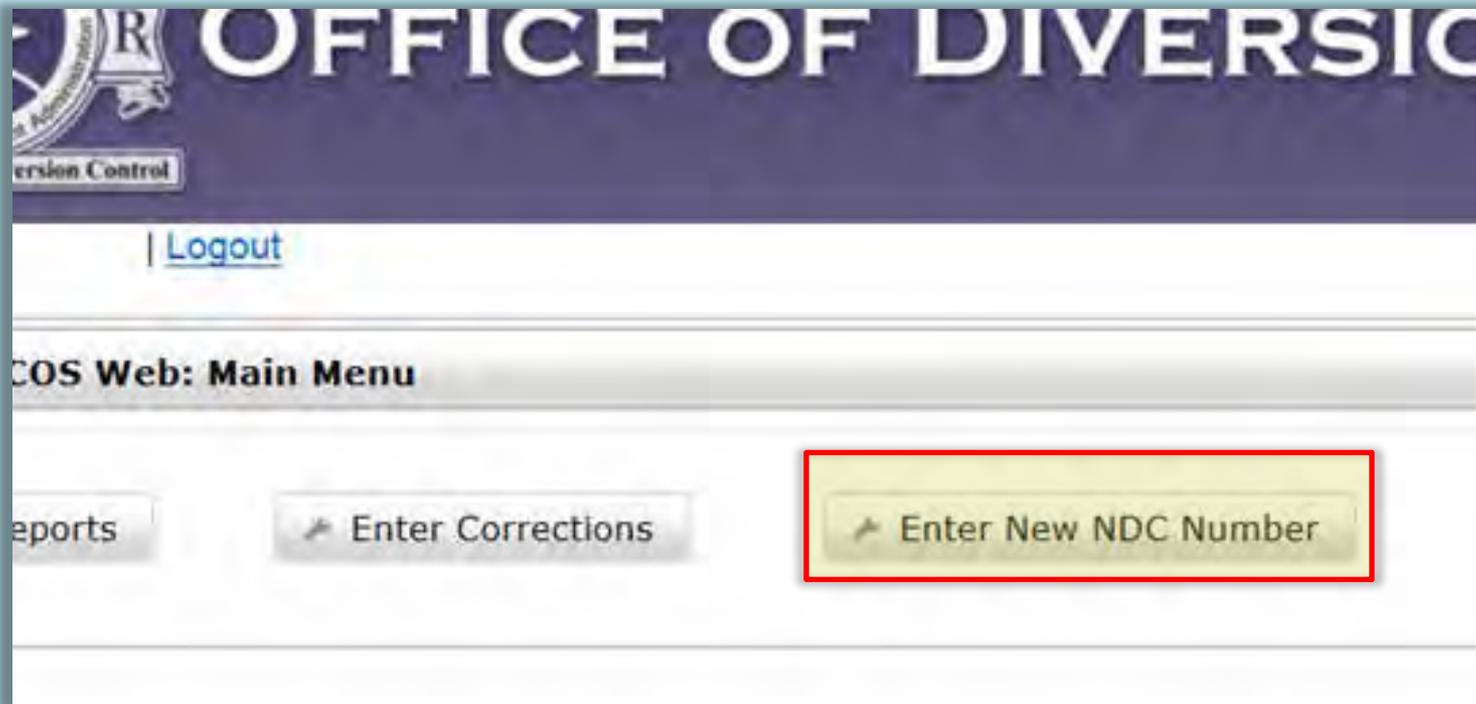


National Drug Code (NDC)

- **Needed in all transactions except for Transaction Codes “7” and “8”**
- **Remember ... 5 – 4 – 2 formatting**
- **NDC must be in ARCOS dictionary to process without error**
- **Only report those materials per 21 C.F.R. § 1304.33**

National Drug Code (NDC)

- NDC reporting and additions made easier by ARCOS Online



National Drug Code (NDC)

- NDC reporting and additions made easier by ARCOS Online

: Add Transaction

Trans Code Key (Enter '=' to set a field to the value from the most recently entered transaction, which is shown below) Help

| Trans Code | NDC Number | Quantity | Unit Code | Strength | Assoc. Reg. # | Order Form # | Trans Date |
|------------|----------------------------------|----------|------------|----------|---------------|--------------|------------|
| P | 54321 -0123 -01 Add NDC | | -Optional- | | | | |

Submit New Transaction Cancel

National Drug Code (NDC)

- NDC reporting and additions made easier by ARCOS Online

ARCOS-WEB: Add NDC Form

NDC Number

Submit Cancel

Upload Scanned Label [?](#)
Help

+ Choose

Current File: **File Not Uploaded, please Upload the file.**

National Drug Code (NDC)

NOTE REGARDING INNER-PACKAGE AND OUTER-PACKAGE NDCs

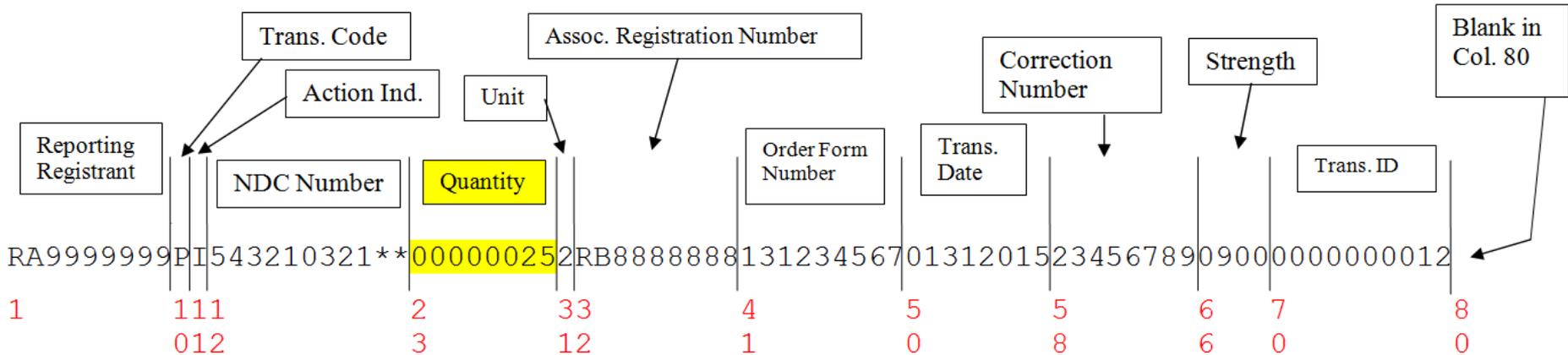
- If different, be sure to use correct NDC
 - If the same, may need to do partial-package reporting

The Transaction Record

National Drug Code (NDC Number)

- ❖ **Common mistakes:**
 - **Improperly formatting the NDC**
 - **Reporting non-reportable or non-scheduled materials**
 - **Reporting products not in the ARCOS dictionary**
 - **Not providing sufficient details on product for ARCOS Unit to add product to the dictionary (if uncertain, please ask!)**

Quantity

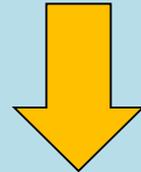
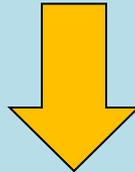
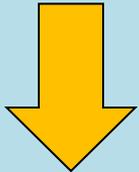


| <u>DATA</u> | <u>FIELD NAME</u> | <u>POSITION</u> |
|---------------|-------------------------------|-----------------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

Quantity

- Can be used in one of two ways, depending on the NDC ...

BULK, RAW MATERIAL

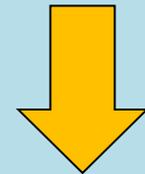
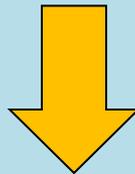
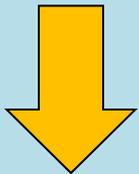


In conjunction with Unit and Strength fields, Quantity represents number of grams, milligrams, micrograms, kilograms, milliliters, or liters

Quantity

- Can be used in one of two ways, depending on the NDC ...

FINISHED PRODUCT



Quantity represents number of packages or, if reporting by individual unit, the number of units

Quantity

❖ Common mistakes:

- Using the Quantity field to indicate the number of units in the package, which is already indicated by (or “built in” to) the NDC
- Reporting a Quantity of zero (EDI text upload and paper reporting only), resulting in uncorrectable error

Quantity

EXAMPLE #1

EXAMPLE #1

*NDC 12345-0123-01
= Oxycodone HCl 5mg Tablet
Package of 100 Tablets*

“Quantity” refers to the **number of packages** of 100 tablets that were involved in the transaction

Quantity

EXAMPLE #2

*NDC 02468-2468-**
= Oxycodone HCl
Raw Material*

*“Quantity” refers to the **number of units of weight or volume** involved in the transaction (used in conjunction with “Unit” and “Strength” fields to indicate unit of measure and purity)*

Unit

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|-----------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyymm) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

RA9999999P I 543210321** 00000025 **2** RB8888888 131234567 01312015 23456789 0900 0000000012

1 111 2 33 4 5 5 6 7 8

012 3 12 1 0 8 6 0 0

Unit

- Can be used in one of two ways, depending on the NDC ...
 - IF NDC REPRESENTS BULK, RAW MATERIAL = ***“Unit” must be one of the following:***
 - ***“1” for micrograms***
 - ***“2” for milligrams***
 - ***“3” for grams***
 - ***“4” for kilograms***
 - ***“5” for milliliters***
 - ***“6” for liters***

Unit

➤ Can be used in one of two ways, depending on the NDC ...

- IF NDC REPRESENTS FINISHED PRODUCT OR PACKAGE SIZE =

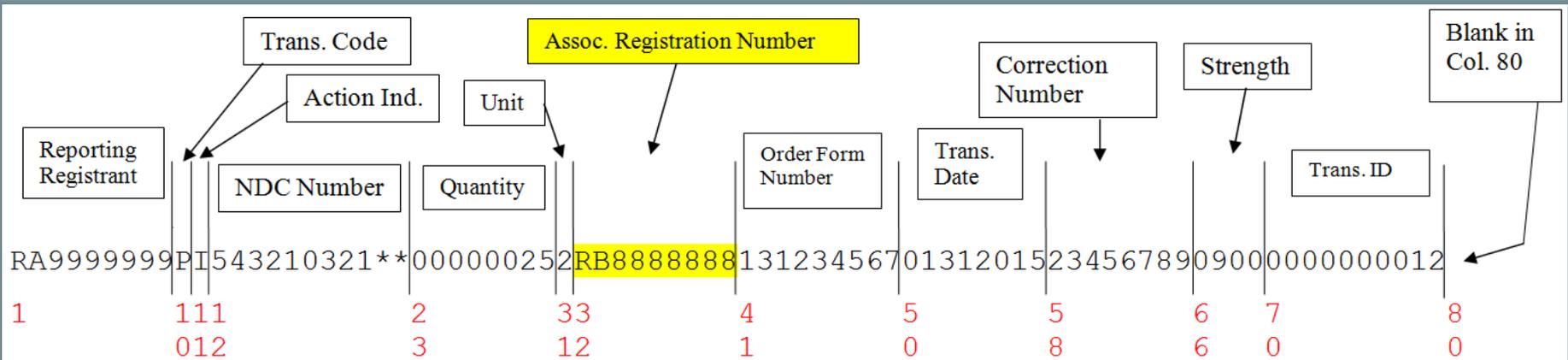
“Unit” can be “D” to multiply the “Quantity” by dozens or “K” to multiply the “Quantity” by thousands (otherwise, must be left blank!)

Unit

❖ Common mistakes:

- Using for *finished package* NDC
- Not using for *bulk, raw material* NDC

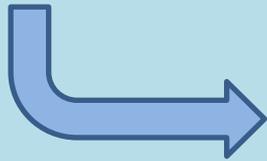
Associate Registration Number



| <u>DATA</u> | <u>FIELD NAME</u> | <u>POSITION</u> |
|------------------|--------------------------------------|-----------------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

Associate Registration Number

- Not required for all types of transactions



Refer to Appendices 1 and 2 of the
ARCOS Registrant Handbook

Section 7: Edit Listings

ARCOS Registrant Handbook

PART IV: REFEREN

- Appendix 1
- Appendix 2
- Appendix 3
- Appendix 4
- Appendix 5
- Glossary

APPENDIX 1 - ARCOS TRANSACTION MATRIX: AUTOMATED REPORTS

[View Text Version](#)

| Transaction | Reporting Registrant | Trans. Code | Action Indicator | NDC | Quantity | Unit | Associate Registrant | Order # |
|---------------------------------|----------------------|-------------|------------------|-----|----------|------|----------------------------|---------|
| | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) |
| INVENTORY TRANSACTIONS | | | | | | | | |
| Sched. Chng. | B | 1 | | B | B | O | | |
| Year-end | B | 3 | | B | B | O | | |
| In-Process | B | 4 | | B | B | O | | |
| Special | B | 5 | | B | B | O | | |
| No Year-end | B | 8 | | | | | | |
| ACQUISITION TRANSACTIONS | | | | | | | | |
| Purchase or Other Receipt | B | P | | B | B | O | ASSOC REG # OR RECALL B, C | H |

CONTACT INFORMATION

Transaction Records

Associate Registration Number

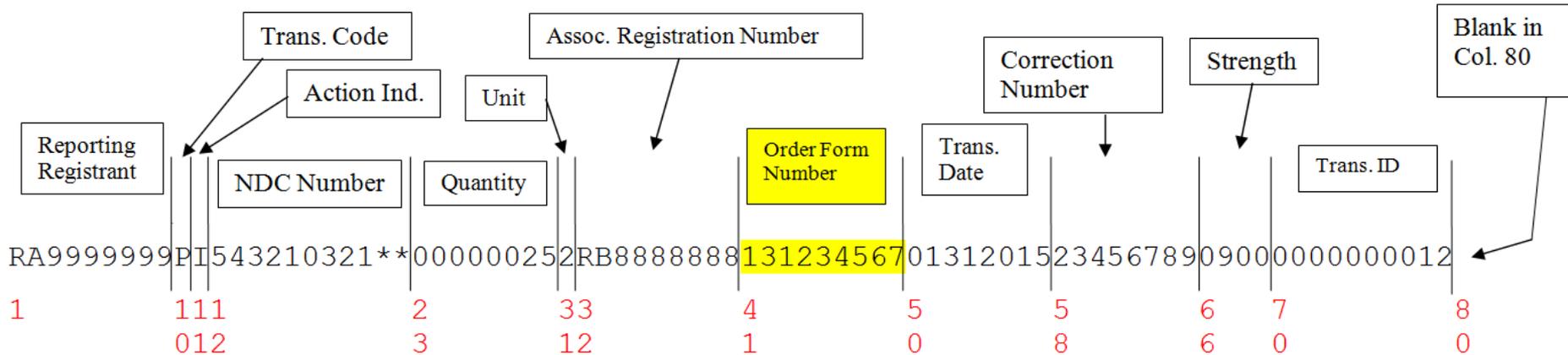
- **Registration of entity on the other end of the transaction**
- **Used to reference local DEA office in instances such as destruction**

Associate Registration Number

❖ Common mistakes:

- Using the field when not needed
- Using a valid but incorrect registration number (e.g. wrong location or retired number)
- Using reporting registrant number as Associate Registrant

Order Form Number



| <u>DATA</u> | <u>FIELD NAME</u> | <u>POSITION</u> |
|---------------|-------------------------------|-----------------|
| RA99999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB88888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

Order Form Number

- Required for *all acquisition or distribution transactions related to C-I and C-II drugs!!!*

NOTE: The ARCOS report should reflect exactly what is on the Order Form

The image shows a portion of a DEA Form -222 (JANUARY 2010). The form is titled 'Schedules' and includes a section for 'Registered as a'. A red box highlights the 'No. of this Order Form' field, which is currently blank. The bottom of the form reads 'DEA Form -222 (JANUARY 2010)' and 'U.S. OFFICIAL ORDER FORMS - SCHEDULE'. The text 'DEA Form -222 (JANUARY 2010)' is located at the bottom left, and 'U.S. OFFICIAL ORDER FORMS - SCHEDULE' is at the bottom right.

Order Form Number

- Required for *all acquisition or distribution transactions related to C-I and C-II drugs!!!*

CSOS TRANSACTION RECORD

| <u>DATA</u> | <u>FIELD NAME</u> | <u>POSITION</u> |
|-------------|-----------------------------|-----------------|
| AA1234567 | REGISTRANT NUMBER | 1-9 |
| P | TRANSACTION CODE | 10 |
| D | ACTION INDICATOR | 11 |
| 000543751** | NDC NUMBER | 12-22 |
| 00000002 | QUANTITY | 23-30 |
| 4 | UNIT | 31 |
| BB1234567 | ASSOCIATE REGISTRANT NUMBER | 32-40 |
| 15X453890 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 91070022 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000088 | TRANSACTION IDENTIFIER | 70-79 |
| Leave Blank | | 80 |
| 000543751** | NDC NUMBER | 81-91 |
| 00000002 | QUANTITY | 92-99 |
| 4 | UNIT | 100 |
| 0900 | STRENGTH | 101-104 |
| Leave Blank | | 105 |

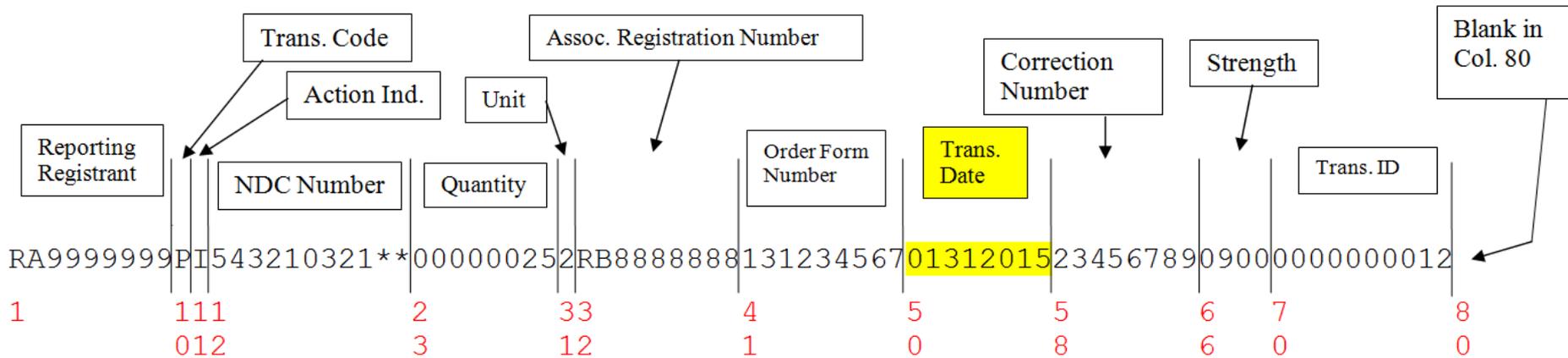
Col. 1 10 11 12 23 31 32 41 50 58 66 70 80 81 92 100 101 105
AA1234567PD000543751**000000024BB123456715X45389001312015910700220900000000088 000543751**000000240900

Order Form Number

❖ Common mistakes

- Not including for a C-I or C-II drug
- Using anything other than the order form number (DEA Form 222) or the CSOS order form number

Transaction Date



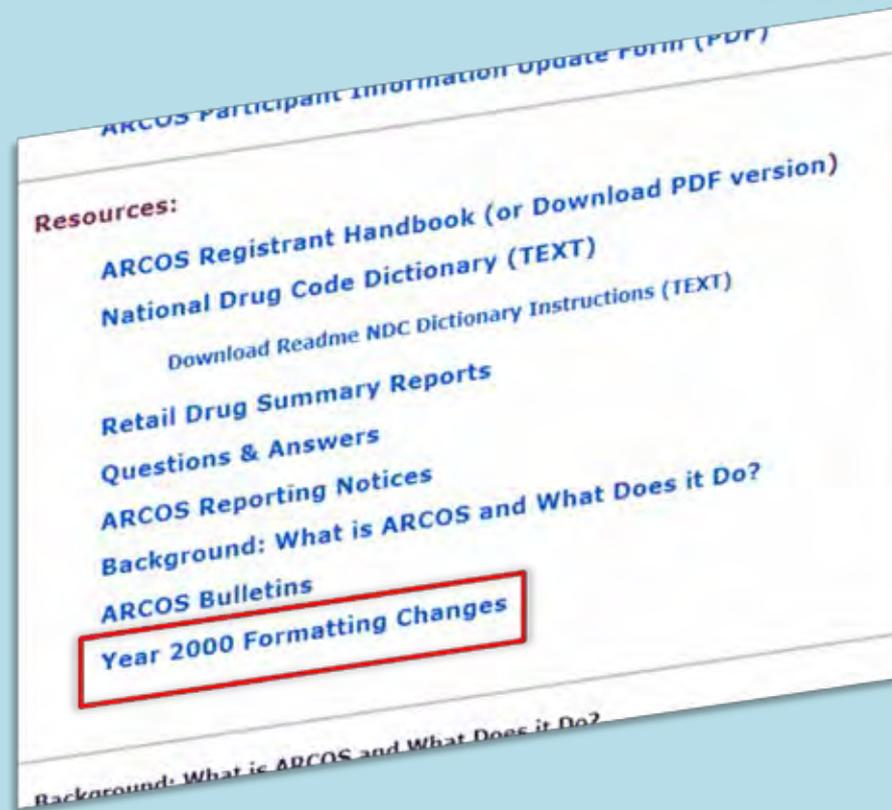
| <u>DATA</u> | <u>FIELD NAME</u> | <u>POSITION</u> |
|---------------|-------------------------------|-----------------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

Transaction Date

- Must reflect the date the product physically arrived or left possession
- If there is a transaction between two ARCOS reporters, it is understood that there will be a difference of at least a few days due to time for shipment

Transaction Date

➤ Must be in **MMDDYYYY** format



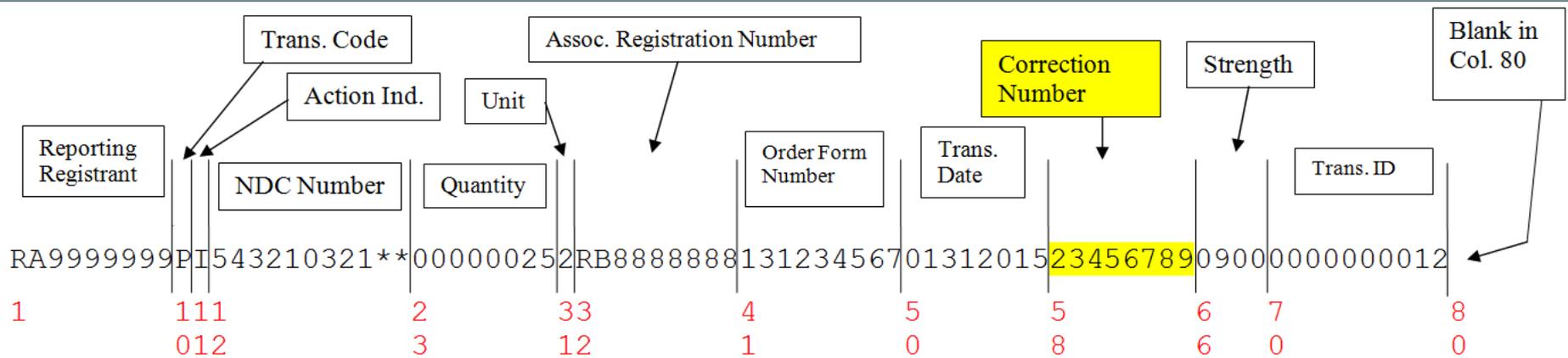
- Mostly an issue in EDI text file uploads
- Exception = ARCOS Online
- Reference “Year 2000 Formatting Changes” on web site

Transaction Date

❖ Common mistakes:

- Improper format or length
- Leaving blank
- Outside of reporting period or in the future
- Invalid date for type of transaction
- Date not representing possession change

Correction Number

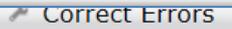
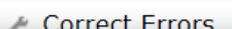
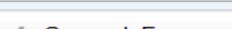
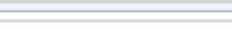


| <u>DATA</u> | <u>FIELD NAME</u> | <u>POSITION</u> |
|---------------|-------------------------------|-----------------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

Correction Number

- Only applies to EDI text file upload and paper reporting (DEA Form 333)
- Not applicable to ARCOS Online!!!

Web: Main Menu

| | |
|-----------------------------------|---|
| RC0403802 Corrections Waiting: 0 |  |
| RD0108200 Corrections Waiting: 12 |  |
| RN0209583 Corrections Waiting: 11 |  |
| RO0153609 Corrections Waiting: 0 |  |
| RW0191419 Corrections Waiting: 11 |  |

 The associate registrant DEA number is invalid.
The Associate Registrant must be one of the DEA Designated Offices for Transaction Code Y,Z, and G.

Correction Number

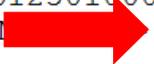
➤ Can be found in one of two places

DATE: 10/16/15 DEPARTMENT OF JUSTICE

| on Ind. | Error(s) | Updated | Correction No |
|---------|----------|------------|---------------|
| | E14 E76 | 10/19/2014 | 23747020 |
| | E14 | 10/19/2014 | 23746998 |
| | E14 E76 | 10/19/2014 | 23747024 |
| | E14 E76 | 10/19/2014 | 23746984 |
| | E14 E76 | 10/19/2014 | 23747029 |

ERROR

TOTAL INPUT RECORDS = 20
TOTAL ERROR RECORDS = 1

RP9999999S 12345012301000000012RS8888888 090220153215432110000000000002P
CORRECTION I  32154321

E31 Unit must be blank, D, or K with this NDC number.

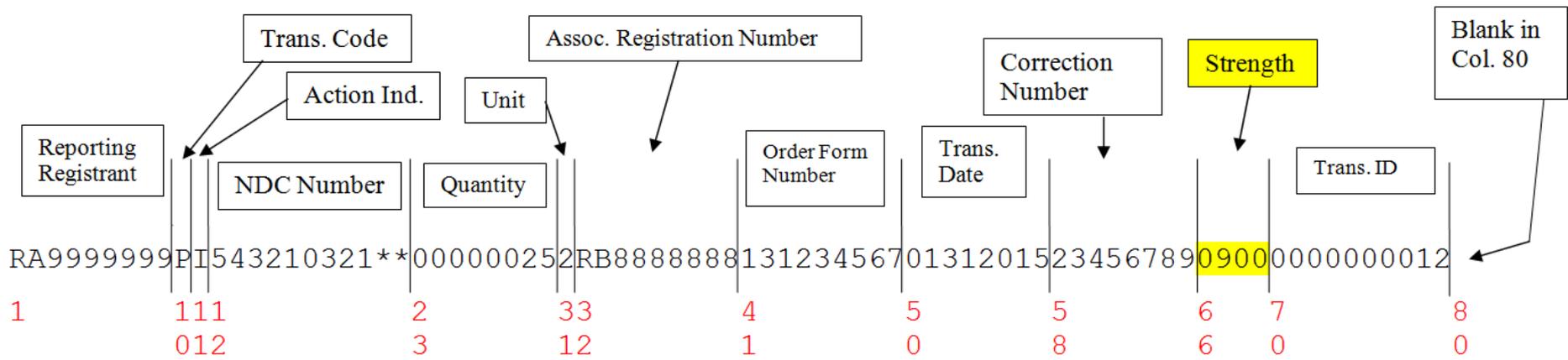
Correction Number

❖ Common mistake:

- Failing to include the Correction Number will result in the creation of a new transaction, and the error will remain uncorrected!!!

Strength

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|----------|
| RA99999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB88888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |



Strength

- Can be used for one of two reasons ...

Partial Package

Partial Package

Purity

Purity

Transaction Records

Strength – Partial Package

- **Quantity must be 1**
- **Activity or inventory**
- **Partial or combined**
- **Percentage of original package size**

Strength – Partial Package *Example*

| Reporting Registrant | Trans. Code | Action Ind. | NDC Number | Quantity | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|-------------|----------|------|----------------------------|-------------------|-------------|-------------------|----------|------------|------------------|
| RP99999999P | 1 | | 12345012301 | 00000001 | | RS88888888 | 151234567 | 12012015 | | 0900 | 0000000002 | |



For this example, **12345-0123-01** represents a package of 100x OXYCODONE HCL TABLETS

Strength – Partial Package *Example*

| Reporting Registrant | Trans. Code | Action Ind. | NDC Number | Quantity | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|-------------|----------|------|----------------------------|-------------------|-------------|-------------------|----------|------------|------------------|
| RP99999999P | | | 12345012301 | 00000001 | | RS88888888 | 151234567 | 12012015 | | 0900 | 0000000002 | |

Note that the Quantity is "1"

"0900" = 90%

90% of 100 tablets = 90 tablets

Strength – Partial Package *Example*

| | | | | | | | | | | |
|----------------------|-------------|-------------|------|----------------------------|-------------------|-------------|-------------------|----------|------------|------------------|
| Reporting Registrant | Trans. Code | Action Ind. | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
| RP99999999P | 12345012301 | 00000001 | | RS88888888 | 151234567 | 12012015 | | 0900 | 0000000002 | |

Registrant RP99999999 is reporting a purchase of 90% of a package of 100x OXYCODONE HCL TABLETS (NDC 12345-0123-01) from registrant RS88888888

Strength – Purity

- **Raw material (required!)**
- **Used in conjunction with Quantity and Unit fields**

Strength – Purity *Example*

| Reporting Registrant | Trans. Code | Action Ind. | NDC Number | Quantity | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|-------------|----------|------|----------------------------|-------------------|-------------|-------------------|----------|------------|------------------|
| RP9999999S | | | 543210321** | 00000005 | 2 | AB8888888 | 152468246 | 12022015 | | 0550 | 0000000003 | |



For this example, **54321-0321-**** represents HYDROCODONE BITARTRATE RAW MATERIAL

Strength – Purity *Example*

| Reporting Registrant | Trans. Code | Action Ind. | NDC Number | Quantity | Unit | Assoc. Registration Number | Order Form Number | Trans. Date | Correction Number | Strength | Trans. ID | Blank in Col. 80 |
|----------------------|-------------|-------------|------------|----------|------|----------------------------|-------------------|-------------|-------------------|----------|------------|------------------|
| RP99999999S | 543210321 | * | 000000052 | 5 | 2 | AB8888888 | 152468246 | 12022015 | | 0550 | 0000000003 | |

Quantity of 5 with Unit of "2" indicates 5 milligrams ...

... and Strength of "0550" indicates a *purity* of 55%

Strength

❖ Common mistakes:

- Indicating a partial package with a Quantity greater than 1
- Interpreting “Strength” to mean the number of milligrams in a tablet
- Leaving the Strength field blank when it is required, or using it when it is not

Transaction Identifier

RA99999999PI543210321**000000252RB888888881312345670131201523456789090000000012

1 111 2 33 4 5 5 6 7 8
012 3 12 1 0 8 6 0 0

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|----------|
| RA99999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB88888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

Transaction Records

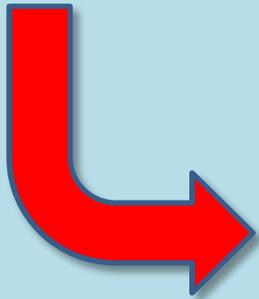
Transaction Identifier

Always a required field!

- Ø EDI/text file = 10 digits
- Ø DEA Form 333 = 5 digits
- Ø ARCOS Online = *read-only!*

Transaction Identifier

∅ Unique to each transaction line of the report – with some *exceptions* ...



§ *Correcting* a transaction from a previously submitted report

§ *Deleting or adjusting* a transaction from a previously submitted report

Column 80

| DATA | FIELD NAME | POSITION |
|---------------|-------------------------------|----------|
| RA9999999 | REPORTING REGISTRANT | 1-9 |
| P | TRANSACTION CODE | 10 |
| I | ACTION INDICATOR | 11 |
| 543210321** | NDC NUMBER | 12-22 |
| 00000025 | QUANTITY | 23-30 |
| 2 | UNIT | 31 |
| RB8888888 | ASSOCIATE REGISTRATION NUMBER | 32-40 |
| 131234567 | ORDER FORM NUMBER | 41-49 |
| 01312015 | TRANSACTION DATE (mmddyyyy) | 50-57 |
| 23456789 | CORRECTION NUMBER | 58-65 |
| 0900 | STRENGTH | 66-69 |
| 0000000012 | TRANSACTION IDENTIFIER | 70-79 |
| (Leave Blank) | | 80 |

| Field | Start Pos | End Pos |
|----------------------------|-----------|---------|
| Reporting Registrant | 1 | 9 |
| Trans. Code | 10 | 10 |
| Action Ind. | 11 | 11 |
| NDC Number | 12 | 22 |
| Quantity | 23 | 30 |
| Unit | 31 | 31 |
| Assoc. Registration Number | 32 | 40 |
| Order Form Number | 41 | 49 |
| Trans. Date | 50 | 57 |
| Correction Number | 58 | 65 |
| Strength | 66 | 69 |
| Trans. ID | 70 | 79 |
| Blank in Col. 80 | 80 | 80 |

Formatting Differences

ARCOS Online

| | | | | | | | | |
|---------------------------|--------------|----------------------------|-----------|----------------------|----------------|----------|-----------|---------------------|
| Reporting Registration | Trans. Code | Assoc. Registration Number | Unit | Order Form Number | Trans. Date | Strength | Trans. ID | Blank in Col. 80 |
| RA 05 99P | 1543210321** | 000000252RB8888888 | 131234567 | 013120152 | 9090000 | 000012 | | |

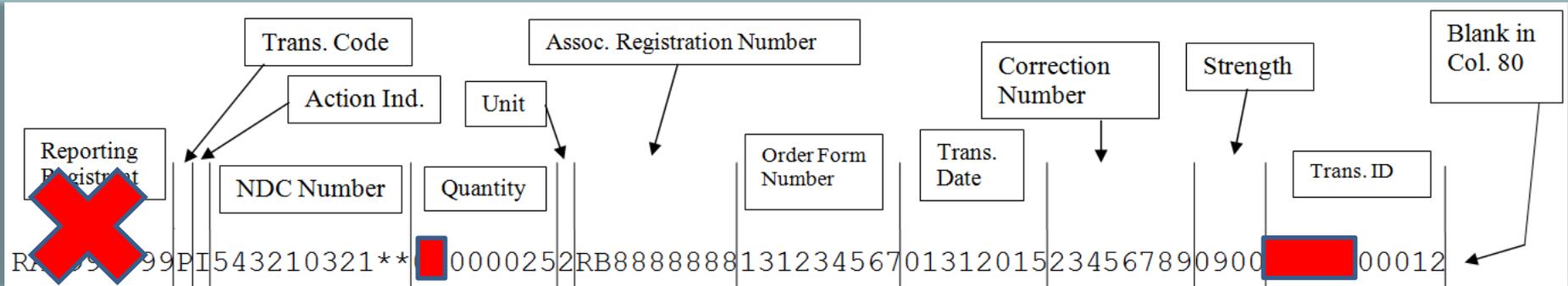


| Trans Code | NDC Number | Quantity | Unit Code | Strength | Assoc. Reg. # | Order Form # | Trans Date |
|------------|--|----------------------|--------------|----------------------|----------------------|----------------------|------------|
| -Select- ▼ | <input type="text"/> <input type="text"/> <input type="text"/> | <input type="text"/> | -Optional- ▼ | <input type="text"/> | <input type="text"/> | <input type="text"/> | |

Transaction Records

Formatting Differences

Paper Reporting – DEA Form 333



| TC | AI | NATIONAL DRUG CODE | | | QUANTITY Nbr. of Packages, Volume or Weight | UNIT | ASSOCIATE REGISTRATION NUMBER | DEA ORDER FORM NUMBER | CORRECTION NUMBER | STRENGTH | TRANSACTION DATE | | | | TRANSACTION IDENTIFIER |
|----|----|--------------------|-----------------|--------------|---|------|----------------------------------|-----------------------|-------------------|----------|------------------|----|----|----|---------------------------|
| | | LABELER CODE | PRODUCT CODE | PKG. CODE | | | | | | | M | M | D | D | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |

Transaction Records

Resources

Resources

Online & Reference Material

DEA Headquarters

Field Offices

Other Agencies

Online & Reference Material

“Resources” Tab

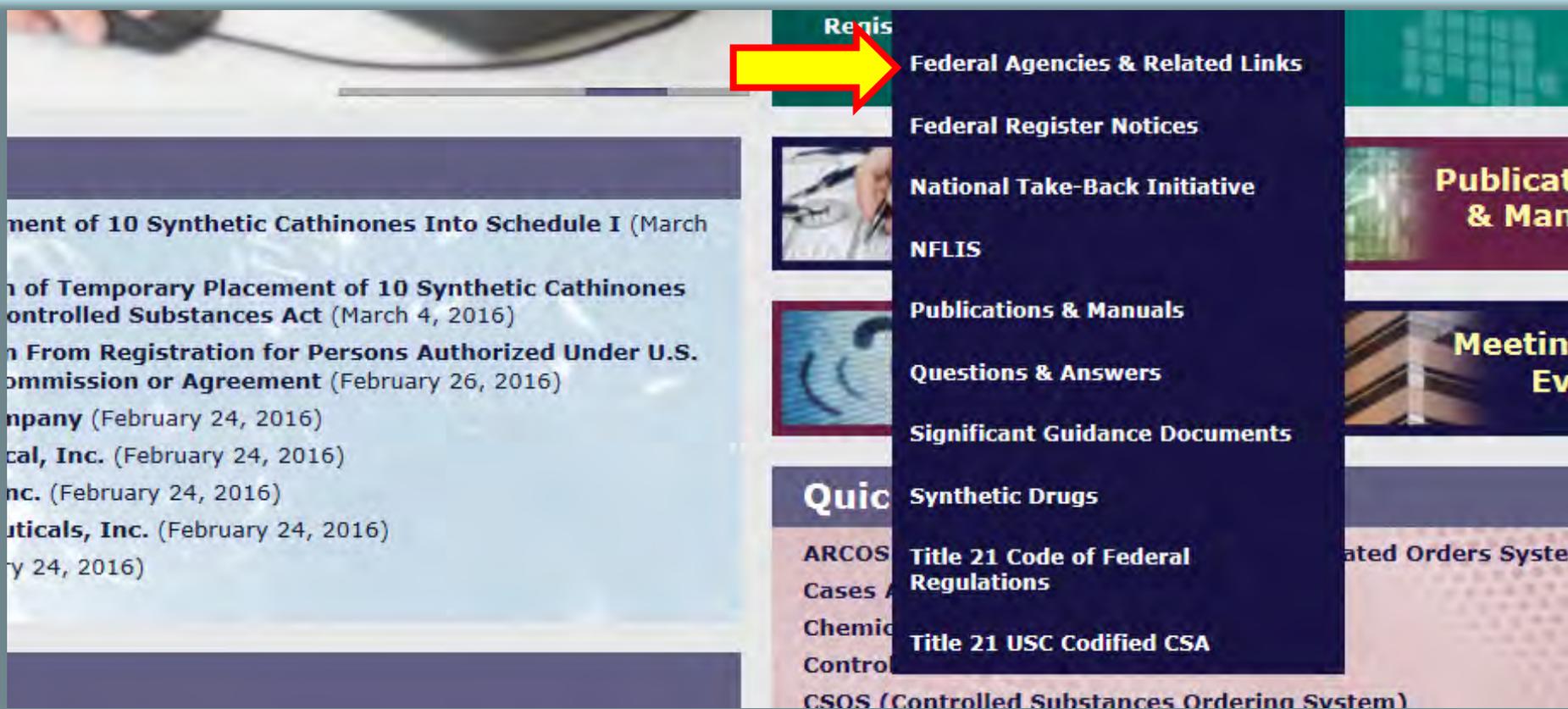


The screenshot shows the website for the Office of Diversion Control. The navigation menu includes 'REGISTRATION', 'REPORTING', 'RESOURCES', and 'ABOUT US'. The 'RESOURCES' tab is highlighted with a red box, and a yellow arrow points to it. Below the navigation menu, there are several sections: 'Cases Against Doctors', 'Chemical Control Program', 'CMEA (Combat Meth Epidemic Act)', 'Controlled Substance Schedules', 'DATA Waived Physicians', 'Drug Disposal Information', 'Drug and Chemical Information', 'E-commerce Initiatives', and 'Federal Agencies & Related Links'. On the right side, there is a section titled 'New Web Browser Security Requirements' with an image of a scientist in a lab coat and safety glasses.

Resources

Online & Reference Material

“Resources” Tab



The image shows a screenshot of a website's navigation menu. A yellow arrow points to the 'Resources' tab, which is highlighted in a dark blue color. The menu items listed under 'Resources' are:

- Federal Agencies & Related Links
- Federal Register Notices
- National Take-Back Initiative
- NFLIS
- Publications & Manuals
- Questions & Answers
- Significant Guidance Documents
- Synthetic Drugs
- Title 21 Code of Federal Regulations
- Title 21 USC Codified CSA

Other visible menu items include 'Regis' and 'Quick'. The background of the website shows a list of news items, including 'Department of 10 Synthetic Cathinones Into Schedule I (March 4, 2016)' and 'Temporary Placement of 10 Synthetic Cathinones Controlled Substances Act (March 4, 2016)'.

Online & Reference Material

ARCOS Website



Online & Reference Material

ARCOS Website



ARCOS Reporting

[ARCOS Online Reporting System](#)

[Announcing ARCOS Online \(PDF\)](#)

[Electronic Data Interchange \(EDI\) Program](#)

[Download ARCOS EDI Request Form \(PDF\)](#)

[ARCOS Personal Computer \(PC\) Field Edit Program](#)

[Download ARCOS PC Field Edit Software Request Form \(PDF\)](#)

[ARCOS Participant Information Update Form \(PDF\)](#)

[Chemical Import/Export
Declarations](#)

[CSOS \(Controlled Substances
Ordering System\)](#)

[Drug Theft/Loss](#)

[Import/Export](#)

[Registrant Record of Controlled
Substances Destroyed](#)

[Quotas](#)

[Reports Required by 21 CFR](#)

[Submit a Tip to DEA](#)

[Year-End Reports](#)

Resources:

[ARCOS Registrant Handbook \(or Download PDF version\)](#)

[National Drug Code Dictionary \(TEXT\)](#)

[Download Readme NDC Dictionary Instructions \(TEXT\)](#)

[Retail Drug Summary Reports](#)

[Questions & Answers](#)

[ARCOS Reporting Notices](#)

[Background: What is ARCOS and What Does it Do?](#)

[ARCOS Bulletins](#)

[Year 2000 Formatting Changes](#)

Online & Reference Material

ARCOS Registrant Handbook

Section 6: Manufacturing Activities

Section 5

5.1

5.2

5.3

6.1 GENERAL

6

6

PART III: SYSTEM OUTPUT

PART IV:

Section 7: Edit Listings

Appendix 1

Appendix 2

Appendix 3

Appendix 4

Contacting Diversion Control

The screenshot shows the homepage of the DEA Office of Diversion Control. At the top left is the logo for the U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control. The main header features the text "U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION" and "OFFICE OF DIVERSION CONTROL" in large white letters on a dark blue background. A search bar is located to the right of the header. Below the header is a navigation menu with five tabs: "HOME", "REGISTRATION", "REPORTING", "RESOURCES", and "ABOUT US". A large yellow banner across the middle of the page displays the website address "www.DEAdiversion.usdoj.gov". On the right side, a vertical menu lists several links: "Program Description", "Contact Us", "Customer Service Plan", "DEA Forms & Applications", "Mailing Addresses", "Meetings & Events", "Privacy Notice", and "What's New". The "Contact Us" and "Mailing Addresses" links are highlighted with red rounded rectangles. Below the navigation menu, there is a section titled "ABOUT US" with a sub-section "ABOUT US" containing a paragraph of text: "The mission of DEA's Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs." Below this text is a link for "Program Description".

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF DIVERSION CONTROL

Search

HOME REGISTRATION REPORTING RESOURCES ABOUT US

www.DEAdiversion.usdoj.gov

Program Description
Contact Us
Customer Service Plan
DEA Forms & Applications
Mailing Addresses
Meetings & Events
Privacy Notice
What's New

ABOUT US

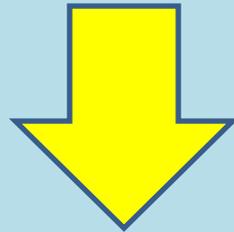
ABOUT US

The mission of DEA's Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

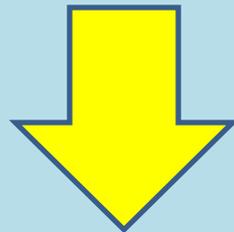
[Program Description](#)

Food and Drug Administration

Food and Drug Administration



Drug Registration and Listing



General Email: EDRLS@fda.hhs.gov

National Library of Medicine

DailyMed

<https://dailymed.nlm.nih.gov/>

The screenshot shows the top portion of the DailyMed website. At the top left, the word "DAILYMED" is displayed in a bold, orange, sans-serif font. Below this is a dark blue navigation bar with three white text links: "ALL DRUGS" (which is underlined), "HUMAN DRUGS", and "ANIMAL DRUGS". A large white search bar with an orange border is centered in the navigation bar, containing the placeholder text "Enter drug, NDC code, drug class, or Set ID". To the right of the search bar is a circular orange search icon. Below the search bar is a blue bar with the text "MORE WAYS TO SEARCH:" followed by four white buttons: "ADVANCED SEARCH", "BROWSE DRUG CLASSES", "LABEL ARCHIVES", and "TABLET/CAPSULE ID TOOL". Below the navigation bar, a light blue box contains the text: "This website contains 83476 drug listings as submitted to the Food and Drug Administration (FDA). At the present time, this Web site does not contain a complete listing of labels for approved prescription drugs." To the right of this text are social media sharing icons for email, Facebook, Twitter, and a plus sign. At the bottom of the screenshot, two light blue boxes are visible: one on the left with the text "NEWS" and one on the right with the text "FDA GUIDANCES & INFORMATION".

ARCOS Help

202-307-8600

ARCOS_Unit@usdoj.gov

Questions